DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 01N–0231]

Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period on a proposed collection of certain information by the agency until [*insert date 45 days after date of publication in the* **Federal Register**]. Under the Paperwork Reduction Act of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice is reopening the comment period for a data collection effort to solicit comments on reporting and recordkeeping requirements obligating holders of approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to submit information on adverse drug reactions, lack of effectiveness, and product defects.

DATES: Submit written or electronic comments on the collection of information by [*insert date 45 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit electronic comments on the collection of information via the internet at: http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 29, 2001 (66 FR 29141), FDA published a notice soliciting comments on reporting and recordkeeping requirements associated with 21 CFR part 510. To give interested persons additional time to submit comments on the proposed data collection, the agency is reopening the comment period until [*insert date 45 days after date of publication in the* **Federal Register**].

Interested persons may submit to the Dockets Management Branch (address above) written comments by [*insert date 45 days after date of publication in the* **Federal Register**]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 8/24/01

August 24, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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